

DEC 30 1998

K982791

510(k) SUMMARY

Submitter: Radiation Oncology Computer Systems, Inc.
6190 Corte Del Cedro
Carlsbad, CA 92009
(760) 929-1811

Contact: Charlene Neblett, Manager, Quality Assurance

Date Prepared: July 31, 1998

Device Name: ROCS TPS

Common Name: Radiation Therapy Treatment Planning System

Classification Name: Accelerator, Linear, Medical, Accessory
Number: 90 IYE (892.5050)

Predicate Device: Radiation Oncology Computer Systems Treatment
Planning System
510(k) notification K862643

Device Description:

ROCS treatment planning system is a collection of software modules that execute well known and documented algorithms to produce radiation dose estimations. All data is user controlled and is in a table look-up format. Information is presented graphically on CRT screens and in hardcopy reports. Various models are available based upon the specific features desired by the customer (e.g., asymmetric jaws, electron pencil beam calculations, etc.) to best meet their clinical needs. The software is designed to run on a PC platform utilizing the Microsoft® Windows NT® operating system. ROCS treatment planning system has been designed to be upgradable in both software features and hardware. All dates are four digit numbers so the system is able to handle the year 2000.

Intended Use:

ROCS TPS (Radiation Therapy Treatment Planning System) is intended to be used for the computation, display, evaluation and output documentation of radiation dose estimations to be submitted for independent clinical review and judgment prior to use. The goal of this system is to provide a tool that will provide consistent results using well documented algorithms. This system does not provide direct or indirect control over any treatment delivery device or system in any form. The device only provides output data in the form of displays, hardcopy prints and/or plots to guide a physician in selecting the optimum patient treatment plan. It is intended to provide a report to be used by a competent health professional such as a radiation oncologist, medical physicist, radiation therapist or dosimetrist.

Technological Characteristics:

The ROCS Treatment Planning System is designed to run on the Microsoft® Windows NT® operating system. The user interface has been based upon the standard Microsoft® Windows® graphical user interface providing ease of use for anyone familiar with windows products. This differs from the predicate device in that the operating system is now Microsoft® Windows NT®; whereas, the predicate device utilized the DOS operating system.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Charlene Neblett
Manager Quality Assurance
Radiation Oncology Computer System, Inc.
6190 Corte Del Cedro
Carsbad, CA 92009

Re: K982791
ROCS TPS
Dated: November 2, 1998
Received: November 3, 1998
Regulatory class: II
21 CFR 892.5050/Procode: 90 MUJ

Dear Ms. Neblett:

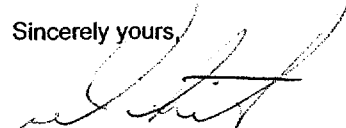
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

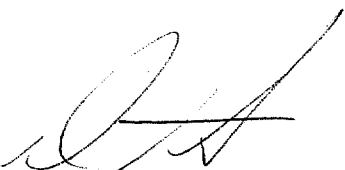

Capt. Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health


Enclosure

INDICATIONS FOR USE

ROCS TPS

ROCS TPS (Radiation Therapy Treatment Planning System) is intended to be used for the computation, display, evaluation and output documentation of radiation dose estimations to be submitted for independent clinical review and judgment prior to use. The device provides output data in the form of displays, hardcopy prints and/or plots to guide a physician in selecting the optimum patient treatment plan. It is intended to provide a report to be used by a competent health professional such as a radiation oncologist, medical physicist, radiation therapist or dosimetrist


(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K982791

Prescription Use 
(Per 21 CFR 801.109)